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STEVEN M MITCHELL PACESETTER INC 701 EAST EVELYN AVENUE SUNNYVALE, CA 94086				FLORY, CHRISTOPHER A		
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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 10/687,846  
Filing Date: October 17, 2003  
Appellant(s): NABUTOVSKY, YELENA

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Theresa A. Takeuchi  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed 29 February 2008 appealing from the Office action mailed 6 October 2006.

**(1) Real Party in Interest**

A statement identifying by name the real party in interest is contained in the brief.

**(2) Related Appeals and Interferences**

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The statement of the status of claims contained in the brief is correct.

**(4) Status of Amendments After Final**

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(5) Summary of Claimed Subject Matter**

The summary of claimed subject matter contained in the brief is correct.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

**(7) Claims Appendix**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(8) Evidence Relied Upon**

### **(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

**Claims 1-28 stand rejected** under 35 U.S.C. 102(b) as being anticipated by Stoop et al. (US Patent 6,370,431).

Regarding claims 1-12 and 23-28, Stoop et al. discloses a method of detecting and preventing ventricular arrhythmias comprising detecting at least two PVCs, determining a difference between their morphologies, and comparing said morphology difference to a predetermined threshold to determine whether to deliver preventative therapy (column 2, lines 10-50); further comprising a step of determining a difference between the coupling intervals of the at least two PVCs and comparing the difference to a predetermined threshold to determine whether to deliver preventative therapy (column 9, line 47 through column 10, line 10); further comprising a step of adjusting the threshold values based on recently detected physiological events (column 5, line 45 through column 7, line 59; column 10, lines 48-54); and delivering preventative therapy in the form of overdrive pacing when the analysis of the PVC parameters indicates that therapy should be delivered (column 2, lines 42-50; column 10, lines 11-54).

Further regarding claims 9 and 10, Stoop et al. states the coupling interval as referring to “the interval from the prior R wave to the VES to the current QT interval,” (column 9, lines 60-62) where the term QT “embraces both the QRS portion and T wave portion of the ventricular signal” (column 3, lines 60-63). It is understood that this is a disclosure of R-R coupling intervals. However, as seen in Fig. 1 the disclosed device of Stoop et al. also comprises P-wave sense circuitry (25) and, so long as the definition of

coupling interval remains consistent, would be capable of using P-R intervals instead of the stated R-R intervals for a functional equivalent result well known in the art.

Further regarding claim 11, Stoop et al. discloses a method for obtaining depolarization information for the current cycle and comparing it to the template generated during the learning phase which involves compiling values of the QT dispersion in different rate bins and determining the difference of respective wave form amplitudes along successive time increments by subtracting amplitude values and integrating over the time domain (column 5, line 66 through column 6, line 17). It is well known that the time integral of a curve in the Cartesian plane is the mathematical equivalent to the area under said curve, and a subtraction of the time integral of one curve (e.g. the current QRS waveform) from that of another (e.g. a stored template) is representative of the difference of the areas under those curves. Therefore, Stoop et al. is understood to disclose a method of analyzing the morphology of the current QRS complex with a previously stored template (which is based on at least 2 previous measurements) by means of comparing the difference in areas under the current waveform and stored template (Figs. 4A-D and 5A-D). Stoop et al. further discloses weighting the results obtained for use in the subsequent determination of intervention (column 9, lines 20-46; column 10, lines 11-34), which is taken to be an equivalent step to assigning a match score that is proportional to the difference in areas under the compared QRS curves.

Regarding claims 13-22, Stoop et al. discloses an apparatus (Fig. 1, pacemaker system) configured to detect and prevent ventricular arrhythmias comprising a detecting

means or sensing circuit (sense circuits 24-26) for detecting at least two PVCs; a processing means (signal processor 27, control microprocessor 20) for determining morphological and coupling interval differences; a comparing means to compare said differences to predetermined thresholds; and a delivery means or pacing circuit (ventricular and atrial pulse generators 15 and 18) for delivering preventative therapy based on said comparisons. (Column 4, lines 7-41).

**(10) Response to Argument**

Applicant proposes that Stoop et al. discloses a pacing system for analyzing QT information on an ongoing basis, comparing a current QT measurement with a compiled mean or measurement based on previous QT data, to determine if a significant adverse condition has occurred. Stoop et al. accomplishes this, in one embodiment, by tracking and evaluating changes in T-wave amplitude and morphology. Applicant then argues that Stoop et al. does not disclose determining differences in morphologies of at least two premature ventricular contractions (PVCs) and comparing the difference to a threshold.

It is the Examiner's position that the T-wave of a QT interval is part of a PVC complex, since a PVC is a type of PQRST waveform (i.e. cardiac beat). Therefore, evaluating the morphology of a T-wave which is part of a PVC reads on the limitation of evaluating the morphology of a PVC since the T-wave forms a part of the morphology of the PVC itself. Further, the disclosure in Stoop et al. of comparing the T-wave data from a current QT interval to a past mean value further reads on the claimed limitation of comparing at least two PVCs. In Stoop et al., establishing that an adverse condition

exists when the current measurement exceeds a predetermined difference from this mean reads on the claimed limitation of comparing the difference between the morphologies to a threshold value, e.g. twice the standard deviation of the mean as admitted by the Applicant. Therefore, it is seen from this that the Stoop et al. disclosure of comparing T-wave morphologies to an average and determining a condition based on a predetermined difference from this average is equivalent to Applicant's claimed invention of comparing PVC morphology (which contains a T-wave) to a threshold (i.e. difference from a predetermined value) in order to determine an adverse condition.

**(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Christopher Flory/

Examiner, Art Unit 3762

Conferees:

/George Manuel/

Primary Examiner, Art Unit 3762

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Supervisory Patent Examiner, Art Unit 3762